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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,387	10/03/2005	Mark S. Michael	FWM0054-01	6046
832 7590 01/29/2008 BAKER & DANIELS LLP 111 E. WAYNE STREET SUITE 800 FORT WAYNE, IN 46802			EXAMINER NGUYEN, CHAU N	
			ART UNIT 2831	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,387

Applicant(s)

MICHAEL ET AL.

Examiner

Chau N. Nguyen

Art Unit

2831

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-19 and 23-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-19 and 23-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-6, 12, 13, 15-17, 19, 26, 30-32 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (5,360,442) in view of Mar (5,483,022).

Dahl et al. (Figures 3 and 5) discloses a metallic lead comprising an outer shell (34) made of a first biocompatible metal, a plurality of wire elements (75, col. 6, lines 45-53) disposed within the shell, the plurality of wire elements being compacted together whereby substantially no voids exist within the outer shell, and an insulation layer (28) disposed around the outer shell. Dahl et al. does not disclose each of the wire elements (75) comprising a metallic shell made of a second biocompatible metal which is a cobalt-nickel-chromium alloy (re claim 5), and being filled with a third biocompatible metal which is silver (re claim 4). Mar discloses a metallic lead comprising a plurality of wire elements, each comprising a cobalt-nickel-chromium alloy shell (26) which is filled with silver (22). It would have been obvious to one skilled in the art to use the wire elements as taught by Mar for the wire elements (75) of Dahl et al. to provide the lead with a greater breaking strength (re claims 1, 30, 31).

The modified lead of Dahl et al. also discloses that the insulation layer includes at least one contact section in the form of a void in the insulation layer (col. 5, lines 45-48) (re claim 2), and the first metal comprises platinum or iridium (re claims 3 and 39). Re claims 6 and 32, although not specifically disclosed by Dahl et al., it would have been obvious to one skilled in the art to twist the wire elements of Dahl et al. together into a bundle to improve the lead flexibility since a

lead comprising a twisted bundle is well-known in the art. Claims 12, 13, 15-17, 19, and 26 are method counterparts of claims 1-6. Dahl et al. also discloses drawing the assembly down to form a wire with a second diameter less than the first diameter (col. 6, lines 45-53).

4. Claims 23, 24, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al.

Dahl et al. discloses a method of making a composite wire, comprising the steps of providing a first tube (34) made of a first biocompatible metal, the first tube having a first diameter, forming a plurality of wire elements (73, 75) into a bundle, at least one of the wire elements made of a second biocompatible metal, at least one of the wire elements made of a third biocompatible metal, inserting the bundle into the first tube to form an assembly, and thereafter drawing the assembly down to form a wire having a second diameter. Dahl et al. does not specifically disclose twisting the bundle. However, it would have been obvious to one skilled in the art to twist the wire elements of Dahl et al. together into a bundle to improve the lead flexibility since a lead comprising a twisted bundle is well-known in the art (re claim 23).

Re claim 24, it would have been obvious to one skilled in the art to modify at least one of the wire elements of Dahl et al. to comprise strands to improve the lead flexibility since a wire element comprising strands is well-known in the art.

Dahl et al. also discloses that drawing the assembly down to form a wire having a second diameter less than the first diameter with substantially no voids existing within the tube (re claim 27), applying an insulation layer to the assembly (re claim 28), and forming at least one contact section in the form of a void in the insulation layer (re claim 29).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3-9, 11, 12, 14-19, 26, and 30-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 8-13, 15, 19, 23 and 25 of copending Application No. 11/203,986 in view of Mar. Claims 5, 8-13, 15, 19, 23 and 25 of the copending application '986 discloses the invention substantially as claimed except for each of the wire elements comprising a metal shell being made of a second biocompatible metal and filled with a third biocompatible metal. Mar discloses a metallic lead comprising a plurality of wire elements, each comprising a biocompatible metal shell filled with a different biocompatible metal. It would have been obvious to one skilled in the art to use the wire elements as taught by Mar for the wire elements of copending application '986 to provide the lead with a greater breaking strength.

This is a provisional obviousness-type double patenting rejection.

7. Claims 23-25, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17 and 25 of copending Application No. 11/203,986. Although the conflicting

claims are not identical, they are not patentably distinct from each other because claims 16, 17 and 25 of copending application '986 does disclose a method of making a composite wire, comprising the steps as claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 12, 23, and 30 have been considered but are moot in view of the new ground(s) of rejection.

Summary

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chau N. Nguyen whose telephone number is 571-272-1980. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego F.F. Gutiérrez can be reached on 571-272-2800 ext 31. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chau N Nguyen/

Chau N Nguyen
Primary Examiner
Art Unit 2831